

DOCKET NO. 17629(AP)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

Applicant: Bakhit et al.  
Serial No.: 10/521,367  
Filed: January 12, 2005  
Customer No.: 051957  
Conf. No.: 2266  
Group Art Unit: 1711

For: COMPOSITIONS AND METHODS COMPRISING  
PROSTAGLANDIN RELATED COMPOUNDS AND  
TREFOIL FACTOR PEPTIDES FOR THE TREATMENT  
OF GLAUCOMA WITH REDUCED HYPEREMIA

Examiner: Not Yet Assigned

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5 pages

STATUS LETTER

Commissioner for Patents  
Alexandria, VA 22313-1450

Dear Sir:

Please provide us with the status of our "Request to Correct Filing Receipt" that we filed on 1 July 2005. (Copy attached.)

Dated: 1/3/06

Telephone: (714) 246-4348  
Facsimile: (714) 246-4249

Respectfully submitted,

By: *Brent A. Johnson*  
Brent A. Johnson  
Registration No. 51,851  
Attorney of Record  
ALLERGAN, INC.- T2-7H  
Legal Department  
2525 Dupont Drive  
Irvine, CA. 92612

Rec'd in USPTO/PCT Office. *Attn:* Date Stamp and Return Card.

Date: *7/1/05*

Serial No.: *10/521,367*

Title: *COMPOSITIONS AND METHODS COMPRISING...*

Dkt. No.: *17629(AP)*

Enclosed Are:

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| <input type="checkbox"/> Specification # _____, Claims # _____ | <input type="checkbox"/> Declaration, Power of Attorney           |
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| <input type="checkbox"/> Priority Documents # _____            | <input type="checkbox"/> Transmittal Letter                       |
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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT

Applicant: Bakht et al.

Serial No.: 10/521,367

Filed: January 12, 2005

Customer No.: 51957

Conf. No.: 2266

Group Art Unit: 1711

For: COMPOSITIONS AND METHODS COMPRISING  
PROSTAGLANDIN RELATED COMPOUNDS AND TREFOIL  
FACTOR PEPTIDES FOR THE TREATMENT OF GLAUCOMA  
WITH REDUCED HYPEREMIA

Examiner: Not Yet Assigned

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NOTICE OF CORRECTION OF FILING RECEIPT

Commissioner for Patents  
Alexandria, VA 22313-1450

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Dear Sir:

Please correct the filing receipt as follows:

## TITLE:

Delete "compound" and insert in place thereof -compounds-

Please charge deposit account 01-0885 if there is a fee required to make this correction.

Respectfully submitted,

Dated: 7-1-05By: Brent A. Johnson

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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/521,367	01/12/2005	1711	1400	17629(AP)		28	3

Allergan Inc  
 2525 Dupont Drive  
 Irvine, CA 92612

CONFIRMATION NO. 2266

## FILING RECEIPT

\*OC000000016008333\*

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Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Peter G Bakhit, Huntington Beach, CA;  
 Richard Graham, Irvine, CA;  
 Orest Olejnik, Coto de Caza, CA;

Power of Attorney: None

## Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US04/27777 08/25/2004

## Foreign Applications

Projected Publication Date: 03/02/2006

Non-Publication Request: No

Early Publication Request: No

## Title

Compositions and methods comprising prostaglandin related compound and trefoil factor family peptides for the treatment of glaucoma with reduced hyperemia

COMPOUNDS

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DOCKET 17629 (AP)

**COMPOSITIONS AND METHODS COMPRISING PROSTAGLANDIN-  
RELATED COMPOUNDS AND TREFOIL FACTOR FAMILY PEPTIDES  
FOR THE TREATMENT OF GLAUCOMA WITH REDUCED  
HYPEREMIA**

5.

**Field of the Invention**

The present invention relates to pharmaceutical compositions comprising prostaglandin-related compounds and trefoil factor family peptides.

10

**Background of the Invention**

**Description of Related Art**

15 Active drugs often have undesirable side effects at their therapeutically effective concentrations. This is particularly problematic for topical use in sensitive areas such as the eyes, where irritation is very difficult to avoid even for relatively mild drugs. As a result, formulating topical ophthalmic drugs is a particularly challenging problem. This is unfortunate because topical ophthalmic  
20 use of drugs has been found to be very useful in managing many conditions affecting the eye such as dry eye, infection, inflammation, allergy, and glaucoma. Glaucoma is a particularly devastating disease of the eye characterized by increased intraocular pressure, which is often treated by topical ophthalmic application of a drug. Glaucoma occurs in about 2% of all persons over the age  
25 of 40 and may be asymptotic for years before progressing to rapid loss of vision. In cases where surgery is not indicated, many drugs have been found to be useful in treating glaucoma by topical application including  $\beta$ -adrenoreceptor antagonists and  $\alpha_2$ -adrenoreceptor agonists. Recently, prostaglandins have been shown to be particularly useful in the topical treatment of glaucoma.

30 Whereas prostaglandins appear to be devoid of significant intraocular side effects, ocular surface (conjunctival) hyperemia, foreign-body sensation, and itching (pruritus) have been consistently associated with the topical ocular use of such compounds, in particular  $\text{PGF}_2\alpha$  and its prodrugs, e.g., its 1-isopropyl-ester,